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3. 510(k) SUMMARY

DEC 0 7 2001

A. Submitter Information:

Name:	Felton International, Inc.
Address:	8210 Marshall Drive Lenexa, KS 66214
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E-mail:	fi@feltonint.com
Contact:	Alan Felton, President
Date:	September 28, 2001

B. Device Information:

Trade/Proprietary Name:	Bi-3M Needle-Free Injector System
Common Name:	Needle-free fluid injector system
Classification Name:	Nonelectrically powered fluid injector (Title 21 CFR §880.5430)
Predicate Devices:	Ped-O-Jet (preamendment device) MEDiVAX (K945548)

C. Description of the Device:

The Bi-3M Needle-Free Injector System consists of a hand-held injector unit to which a multiple-dose vial of vaccine or medication can be attached. The unit is spring-powered and is connected to its hydraulic fluid power source, which is operated by a foot pump.

The Bi-3M Needle-free Injector System is identical to the Bi-3 injector which was first introduced into the public health system in Russia in 1974. Five modifications are made to the Bi-3M, the subject device of this submission. Three modifications to the injector are as follows: 1) the injected volume is fixed at 0.5 mL, whereas the Bi-3 can adjust to variable volume delivery (0.1 to 1.0 mL); 2) the device has a single nozzle for subcutaneous delivery, whereas the Bi-3 has three nozzle attachments for subcutaneous, intramuscular, and intradermal delivery; 3) a vial mount assembly holds the vial in place with a vial cap mount, whereas the original Bi-3 has metal clamps to hold the vial in place.

The fourth and fifth modifications were made for the most significant feature of the Bi-3M needle-free injector system: the presterilized, single-use protector cap, and a redesign of the distal end of the hand unit to accommodate the cap. The cap is attached to the injector head before each injection and automatically removed before the next injection to prevent cross-contamination. All five modifications do not alter the basic mechanics of the device, or any component or aspect of the fluid path. The effectiveness in preventing cross-contamination is documented in the safety study discussed under Section 7.B.

D. Intended Use of the Device

The Bi-3M is designed to administer vaccines or medicines to the subcutaneous tissue by penetrating the skin under high pressure. It is intended for high-workload multiple-patient use by a health care professional, such as in mass immunization programs.

E. Technological Characteristics in Comparison to Predicate Devices

Similar to the Ped-O-Jet and MEDiVAX devices, Bi-3M is a needle-free injector system that consists of a hand-held injector unit and a connecting power source that is activated by a foot pump. The Bi-3M uses hydraulic fluid, which is identical to the power source of the Ped-O-Jet; MEDiVAX is powered by compressed air. All three devices hold a manufacturer's multiple-dose vial in position on the hand unit. A vial mount assembly that locks the vial cap to the Bi-3M hand unit holds the medicine vial in position. A 'U'-shaped clamp holds the vial cap in position on the Ped-O-Jet unit. The vial is attached first to a removable vial holder that is attached to the hand unit of MEDiVAX. The delivery of medication from the vial to the primary container in the hand unit is through stainless steel in all three devices. A presterilized protector cap is placed on the nozzle end of the Bi-3M before each injection to prevent cross-contamination; this cap is automatically removed after each use. MEDiVAX has a removable protector shield for the same purpose. No protective feature is on the preamendment Ped-O-Jet device.

All three devices have removable injector heads to facilitate cleaning and sterilization of the components in contact with the medication fluid path and human skin. These components require steam sterilization before each injection session.

F. Nonclinical Performance Tests

A battery of performance testing was done to assess the substantial equivalency of the Bi-3M to Ped-O-Jet. Based on results of testing for dosage accuracy, there was no significant difference between the two injectors. Penetration, focus, force, and stream quality tests showed the two devices to be similar in these parameters. Additionally, environmental testing that tested the Bi-3M at temperature extremes and after free fall indicated consistent functionality. Operation of the Bi-3M produces sound that is below the exposure limits set by OSHA.

G. Safety Tests

The effectiveness of the Bi-3M to prevent cross-contamination was tested with an in vitro model designed to produce a high probability of contamination. In this study, an injection was made first into a contaminated (fluorescein) fixture, then into a clean vessel to assess the downstream contamination. The results showed the Bi-3M had a 99.8% clean sample rate, whereas Ped-O-Jet had a 54% clean sample rate. The one Bi-3M sample for which fluorescein was reported in the downstream collection did not have any fluorescein evident in the protector caps, which indicates that the fluorometer reading was an error. The high clean sample rate by the Bi-3M in this study that was designed to have a high rate of contamination is indicative that cross-contamination is unlikely with this device.

H. Conclusions:

The Bi-3M injector system is designed similarly to the cited predicate devices. Based on the results of the performance tests for dose accuracy, penetration, focus, force, and stream quality, the Bi-3M has demonstrated substantial equivalence to the Ped-O-Jet predicate device. Furthermore, the results of the safety test demonstrated a high level of safety relative to cross-contamination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 7 2001

Mr. Alan Felton
President
Felton International, Incorporated
8210 Marshall Drive
Lenexa, Kansas 66214

Re: K013256
Trade/Device Name: Bi-3M Needle Injector System
Regulation Number: 880.5430
Regulation Name: Needle-Free Fluid Injector System
Regulatory Class: II
Product Code: KZE
Dated: September 28, 2001
Received: October 1, 2001

Dear Mr. Felton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Applicant: Felton International, Inc.

Device Name: Bi-3M Needle-free Injector System

2. INDICATIONS FOR USE

This needle-free fluid injector system is indicated for the delivery of vaccines or medications to the subcutaneous tissue by penetrating the skin under high pressure. This device is to be used by a health care professional only.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013500